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**Filed** : **March 1, 2004**

## **REMARKS**

The foregoing amendments and the following comments are responsive to the objections and rejections set forth by the Examiner in the August 28, 2007 Office Action.

Claims 1-16 and 24-30 are pending in this application. The Examiner rejected Claims 1-16 and 24-30. In particular, the Examiner rejected Claims 1-16 and 24-30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner rejected Claims 1-7, 10, 12-14, 16, and 24-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2002/0110485 A1 ("the Stringer et al. publication").

The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 6,264,601 ("the Jassawalla et al. patent"). The Examiner further rejected Claims 9 and 15 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 6,769,871 ("the Yamazaki patent"). The Examiner further rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 5,823,987 to Elgas et al. ("the Elgas et al. patent").

The Examiner rejected Claims 1-7, 10, 12-14, 16, and 24-30 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 4,919,802 to Katsura et al. ("the Katsura et al. '802 patent"). The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 4,919,802 ("the Katsura et al. '802 patent"), further in view of U.S. Patent No. 6,264, 601 to Jassawalla et al. The Examiner rejected Claims 9 and 15 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 4,919,802 ("the Katsura et al. '802 patent), further in view of U.S. Patent No. 6,769,871 ("the Yamazaki patent"). The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 4,919,802 ("the Katsura et al. '802 patent), further in view of U.S. Patent No. 5,823,987 ("the Elgas et al. patent"). In view of the following discussion, reconsideration of the application is respectfully requested.

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**REJECTION OF CLAIMS 1-16 and 24-30 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

The Examiner rejected Claims 1-16 and 24-30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

**Claims 1, 24, and 30**

The Examiner alleged that the claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In order to expedite prosecution of the patent, Applicants have canceled the phrase "wherein the impeller does not substantially impart any force either to drive inflow of blood to, or outflow of blood from, the chamber". The deleted phrase was, however, supported by Figure 1, which accompanied the specification. The same arguments apply to Claims 24 and 30, both of which have had the pumping requirement into or out of the chamber deleted. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 1, 24, and 30 under 35 U.S.C. § 112, first paragraph.

**Claims 2-16**

Claims 2-16, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

**Claims 25-29**

Claims 25-29, which depend from Claim 24, are believed to be patentable for the same reasons articulated above with respect to Claim 24, and because of the additional features recited therein.

**REJECTION OF CLAIMS 1-7, 10, 12-14, 16, and 24-30 UNDER 35 U.S.C. § 102(b)**

The Examiner rejected Claims 1-7, 10, 12-14, 16, and 24-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2002/0110485 A1 ("the Stringer et al. publication").

**Claim 1**

Stringer et al. does not appear to disclose or teach a filter for removal of air from blood wherein an impeller is located within an axially elongate, cylindrical gas removal chamber, said impeller being spun by an electric motor, wherein the impeller, the blood inlet port, the blood outlet port and the gas removal port all are located in the chamber. Furthermore the impeller of Stringer et al. does not appear to functions to accelerate the blood within the chamber to velocities faster than those of the blood entering the chamber at the blood inlet port. The Stringer et al. disclosure does not appear to disclose or teach a structure wherein the impeller is not separated from the gas removal port by either a constriction or a mesh-type particulate filter.

In contrast, in an embodiment of the invention, air is removed from blood within a chamber defined by a cylindrical housing, the system comprising an impeller located within the chamber, driven by a motor, that actively spins the blood circumferentially about an axis to generate centrifugal forces on the blood to force the buoyant air to migrate radially toward the center of the chamber within the housing where it is removed by a gas vent operably connected proximate the top of the centerline of the chamber. Furthermore, the chamber, which is described in the text supporting Figure 1 as being an axially elongate cylinder, has no restriction or constriction between the blood inlet, the blood outlet and the impeller and the gas vent is not separated from the impeller by a particulate filter. The definition of a cylinder requires straight sides and that geometry precludes any substantial diameter changes such as are found in Stringer et al. Furthermore, in all embodiments of the invention, the impeller is able to directly rotate the blood at a much higher rotational rate than could a passive tangential inlet line where the blood flow is generated by the impeller of a blood pump to push or pull blood through the gas removal chamber, such as appears to be found in Stringer et al.

In summary, there appears, in Stringer et al., to be no suggestion or disclosure of a single, cylindrical chamber comprising an impeller within the chamber that spins the blood to force gas to migrate to the center by centrifugal effects where it is removed. The Stringer et al. patent publication appears not to disclose a centrifugal type gas removal apparatus wherein the blood is spun by an impeller to generate the centrifugal

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forces by a motor driven impeller within the same chamber as the gas vent. There appears to be no motivation or suggestion to use the impeller device as a gas removal apparatus since the impeller is not located within the same chamber where the air is removed from the blood. Furthermore, Stringer et al. appear not to locate their impeller between the particulate filter and the gas vent.

Because the Stringer et al. reference cited by the Examiner does not appear to disclose, teach or suggest an apparatus adapted from removing air bubbles from blood, comprising an axially elongate, shell defining a chamber, an impeller disposed within the chamber, a motor operably connected to the impeller, a gas vent in fluid communication with the central axis of the chamber, a blood inlet port; and a blood outlet port located at the radial periphery of said chamber; wherein the chamber diameter is approximately constant in the region between the blood inlet port, the blood outlet port, and the impeller, wherein the impeller is configured to rotate a volume of blood within the chamber about the central axis of the shell thus forcing air bubbles within the volume of blood to migrate radially inward in response to centrifugal forces imparted on the volume of blood by the rotation of said blood, Applicants assert that Claim 1 is not anticipated by Stringer et al. Applicants therefore respectfully submit that Claim 1 is patentably distinguished over the cited reference and Applicants respectfully request allowance of Claim 1.

**Claims 2-7, 10, 12-14, and 16**

Claims 2-7, 10, 12-14, and 16, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

**Claims 24 and 30**

Although Claims 24 and 30 have different language than Claim 1, Claims 24 and 30 are believed to be patentable for similar reasons, and because of the different features recited therein. Applicants believe that Claims 24 and 30 are patentably distinguished from the Stringer et al. reference and respectfully request allowance of Claims 24 and 30.

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**Claims 25-29**

Claims 25-29, which depend from Claim 24, are believed to be patentable for the same reasons articulated above with respect to Claim 24, and because of the additional features recited therein.

**REJECTION OF CLAIM 8 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Stringer et al. publication in view of U.S. Patent No. 6,264,601 ("the Jassawalla et al. patent").

**Claim 8**

Claim 8, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

**REJECTION OF CLAIMS 9 and 15 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claims 9 and 15 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 6,769,871 ("the Yamazaki patent").

**Claims 9 and 15**

Claims 9 and 15, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

**REJECTION OF CLAIM 11 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 5,823,987 ("the Elgas et al. patent").

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### **Claim 11**

Claim 11, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

### **REJECTION OF CLAIMS 1-7, 10, 12-14, 16, AND 24-30 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claims 1-7, 10, 12-14, 16, and 24-30 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 4,919,802 ("the Katsura et al. patent").

### **Claim 1**

Neither Stringer et al. nor Katsura et al. disclose or teach a filter for removal of air from blood wherein an impeller is located within an axially elongate, cylindrical gas removal chamber, said impeller being spun by an electric motor. Neither Stringer et al. nor Katsura et al. appear to disclose a structure where the impeller, the blood inlet port, the blood outlet port and the gas removal port all are located in the chamber. Neither Katsura et al. nor Stringer et al. appear to disclose a blood filter wherein an impeller functions to accelerate the blood to velocities faster than those of the blood entering the chamber at the blood inlet port, and further wherein the impeller is not separated from the gas removal port by a constriction or a mesh-type particulate filter.

In contrast, in an embodiment of the invention, air is removed from blood within a chamber defined by a cylindrical housing, the system comprising an impeller located within the chamber, driven by a motor, that actively spins the blood circumferentially about an axis to generate centrifugal forces on the blood to force the buoyant air to migrate radially toward the center of the chamber within the housing where it is removed by a gas vent operably connected proximate the top of the centerline of the chamber. Furthermore, the chamber, which is described in the text supporting Figure 1 as being an axially elongate cylinder, has, by the definition of cylinder, no restriction or constriction between the blood inlet, the blood outlet and the impeller. The gas vent of the Applicants' invention is not separated from the impeller by a particulate filter. In all embodiments of the invention, the impeller is able to rotate the blood at a much higher

rotational rate than could a passive tangential inlet line where the blood flow is generated by the impeller of a blood pump, thus more efficiently centrifuging the lighter air bubbles toward the center of the chamber and separating them from the heavier blood components which will move more efficiently to the outside where they are drawn off by the blood outlet.

In summary, there appears, in either Katsura et al. or Stringer et al., to be no suggestion or disclosure of a single, cylindrical chamber comprising an impeller within the chamber that spins the blood to force gas to migrate to the center by centrifugal effects where it is removed. Neither Katsura et al. nor Stringer et al. appear to disclose a centrifugal type gas removal apparatus wherein the blood is spun by an impeller to generate the centrifugal forces by a motor driven impeller within the same chamber as the gas vent. There appears to be no motivation or suggestion to use the impeller device as a gas removal apparatus since the impeller of Stringer et al. is not located within the same chamber where the air is removed from the blood and Katsura et al. does not have an impeller. Furthermore, Stringer et al. appear not to locate their impeller between the particulate filter and the gas vent.

Because neither the Katsura et al. nor the Stringer et al. references cited by the Examiner appear to disclose, teach or suggest an apparatus adapted from removing air bubbles from blood, comprising an axially elongate, shell defining a chamber, an impeller disposed within the chamber, a motor operably connected to the impeller, a gas vent in fluid communication with the central axis of the chamber, a blood inlet port; and a blood outlet port located at the radial periphery of said chamber; wherein the chamber diameter is approximately constant in the region between the blood inlet port, the blood outlet port, and the impeller, wherein the impeller is configured to rotate a volume of blood within the chamber about the central axis of the shell thus forcing air bubbles within the volume of blood to migrate radially inward in response to centrifugal forces imparted on the volume of blood by the rotation of said blood, Applicants assert that Claim 1 is not anticipated by Stringer et al. or Katsura et al., alone or in combination. Applicants therefore respectfully submit that Claim 1 is patentably distinguished over the cited references and Applicants respectfully request allowance of Claim 1.

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**Claims 2-7, 10, 12-14, and 16**

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**Claims 24 and 30**

Although Claims 24 and 30 have different language than Claim 1, Claims 24 and 30 are believed to be patentable for similar reasons. Applicants believe that Claims 24 and 30 are patentably distinguished from the Stringer et al. and Katsura et al. references and respectfully request allowance of Claims 24 and 30.

**Claims 25-29**

Claims 25-29, which depend from Claim 24, are believed to be patentable for the same reasons articulated above with respect to Claim 24, and because of the additional features recited therein.

**REJECTION OF CLAIM 8 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Stringer et al., in view of U.S. Patent No. 4,919,802 to Katsura et al., further in view of U.S. Patent No. 6,264,601 ("the Jassawalla et al. patent").

**Claim 8**

Claim 8, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

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### **REJECTION OF CLAIM 11 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al., in view of U.S. Patent No. 4,919,802 to Katsura et al., further publication in view of U.S. Patent No. 5,823,987 ("the Elgas et al. patent").

### **Claim 11**

Claim 11, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

### **NO DISCLAIMERS OR DISAVOWALS**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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**CONCLUSION**

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Examiner is cordially invited to contact the undersigned such that any remaining issues may be promptly resolved.

Respectfully submitted,

Dated: 28 November 2007

By: Jay A Lenker  
Jay A. Lenker, Inventor  
(949) 494-3645 Home  
(949) 322-6929 Mobile